

Appl. No. 10/801,168
Amendment Dated October 31, 2006
Reply to Office Action of September 15, 2006

Amendments to the Drawings:

The attached 13 sheets of drawings includes replacement line drawings for all of the originally-submitted figures. No new matter has been added.

Fig. 8 has been canceled because it is identical to Fig. 6 and is reflected in the annotated sheet. The brief description has been amended to reflect the cancellation.

Attachment: 13 Replacement Sheets
1 Annotated Sheet Showing Canceled Fig. 8

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Remarks:

Reconsideration of the application is requested. Claims 1-30 are now in the application. Claims 1 and 9 have been amended. Claims 15-30 have been added.

Claim 1 was amended to broaden the scope of the claimed invention. Support for the change to claim 1 can be found in the originally filed specification at page 50, line 16. The amendment to claim 1 was not made for reasons relating to the prior art or the statutory requirements for obtaining a patent. Claim 15 was added and is identical to the originally-filed claim 1 in scope.

Claim 9 was amended to correct an obvious error. The term current has been replaced with voltage.

Claims 16-30 relate to a method of using the apparatus according to claim 1. Such method claims should be rejoined and allowed when the underlying base claims (i.e. claim 1-15) are allowed. See MPEP § 821.04(b).

Before addressing the rejections made by the Examiner, Applicant offers some the following insight to the invention.

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The prior art has demonstrated that (direct current) electrical stimulation of tissue can be therapeutic. The key underlying science was not at all understood until the breakthrough analysis of Reich and Tarjan using direct (as opposed to inducted) fields; a copy of this paper is included as Appendix II. After a detailed study of a number of diverse and independent applications of electrical therapies, a clear and unequivocal conclusion emerged. Only in those applications where a sufficient quantity of electrical charge was caused to be transported across the wound site would a beneficial outcome be observed. The authors further conclude that two parameters are paramount in judging between various electrical modalities: "These two parameters are the average spatial current density and the effective duty cycle. These parameters can be combined with the treatment time to provide the absolute charge density transferred."

As discussed in the prior-art section of the instant application, the treatment of tissue by direct application of current to treat tissue, especially nervous tissue, is limited in practice due to the associated risk of infection.

The primary objective of the instant application is effective charge transport in tissue created by specific electric fields

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that are induced by related magnetic fields. It follows, that the claims are directed to an apparatus that has the mechanical features to achieve this objective. Applicants review of the prior art leads them to concluded that none of the cited references teach or suggest an apparatus capable of achieving the object; the reasons are detailed below.

The instant application teaching provides an apparatus and a method to achieve the objective: high electric field strengths, long effective duty cycles, and the ability to repeat the process (cycle) continuously for an uninterrupted extended duration achieve absolute charge transport.

While the Applicant acknowledges that the various separate components of the current teaching are known: in themselves, they are not novel. However, the apparatus and method that combine and utilize the various elements is novel and not obvious. No other cited or known method of therapeutic electrical induction is able to produce the combined requisite electrical outputs taught herein.

Now referring to the specific rejections in the Office action, in item 3 of the Office action, the Examiner rejected claims 2 and 14 as being directed to non-statutory subject matter. More

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specifically, the Examiner stated that, "The positive recitation of the shape of the magnetic field wave is not statutory subject matter." MPEP § 2106 sets the examination guidelines for interpreting 35 U.S.C. § 101. "USPTO personnel must first identify whether the claim falls within at least one of the four enumerated categories of patentable subject matter recited in section 101 (i.e., process, machine, manufacture, or composition of matter);" MPEP §2106.IV.B. The Examiner must then determine if the claims are directed to nothing more than abstract ideas, natural phenomena, and laws of nature; MPEP § 2106.IV.C. To be patentable the claimed invention must be a practical application of an abstract idea, law of nature, or natural phenomenon; MPEP §2106.IV.C.2. The practical test is whether the invention as claimed "(A) 'transforms' an article or physical object to a different state or thing; or (B) otherwise, produces a useful concrete, and tangible result..."

Claims 2 and 14 and their intervening base claims are repeated *inter alia* below.

Claim 1 (Currently Amended). An apparatus for creating therapeutic charge transfer in tissue, comprising a coil generating a changing magnetic field to induct an electric field in the tissue exceeding 1 mV/cm when said coil is 5 cm from the tissue.

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Claim 2 (Original). The apparatus according to claim 1, wherein said magnetic field is saw-tooth shaped.

Claim 14 (Original). The apparatus according to claim 1, wherein said magnetic field has an asymmetric waveform.

To begin the Section 101 analysis, claims 1, 2, and 14 are all directed to an "apparatus". An apparatus is a machine, which is one of the enumerated exceptions in the statute.

Next, the invention as described in claims 2 and 14 is patentable subject matter because it involves an apparatus that applies a specific waveform, which is a phenomena of nature, to produce a useful concrete, and tangible result. The apparatus has been studied at the University of Miami Medical School, The Miami Project to Cure Paralysis, Advanced Wound Recover of Boston, and Johns Hopkins Medical School to obtain therapeutic results. For example, *in vivo* tests have been conducted in which burns on pigs were treated using the apparatus. The wounds that were treated healed faster than untreated wounds in the control wounds. Appendix I provides a report of the experiment and results.

Claims 2 and 14 are directed to apparatuses that create therapeutic charge transfer in tissue by generating a saw-tooth

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or asymmetric shaped magnetic field to induct an electric field in the tissue exceeding 1 mV/cm when said coil is 5 cm from the tissue. The invention is useful because treating tissue by placing it near the magnetic field creates a charge transfer within the tissue, which in turn promotes healing. The invention described is tangible because the apparatus is more than merely recited; structures such as the coil are specified in the base claim, claim 1. The invention creates a concrete result; the device has been used repeatedly to produce results; see for example Appendix I.

Applicants are not intending to claim a waveform. Rather, Applicants intent is to claim an apparatus that uses a coil to generate a magnetic field to treat tissue. Creating and utilizing magnetic fields with specific qualities (i.e. claims 2 and 14) with the device have been discovered to have therapeutic utility. Inventors do not intend to claim the waveform and prevent others from using it with different devices in different applications.

For these reasons, claims 2 and 14 when read with the limitations of their underlying base claim, claim 1, are the type of statutory subject matter that is to be patentable under 35 USC § 101.

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In item 5 of the Office action, the Examiner rejected claims 1-3 and 14 as being fully anticipated by Canedo (US 2003/0171640) under 35 U.S.C. § 102(e).

Applicant respectfully notes that Canedo has a filing date of March 8, 2002. See 35 U.S.C. § 102(e). As set forth in the Declaration of record, the instant application is a continuation-in-part application of copending U.S. Application 10/035,854, filed November 9, 2001, now abandoned. Pursuant to 35 U.S.C. § 120, applicant is entitled to the priority date of the parent application. See MPEP § 201.11. Section 201.11 further explains, "Any claim in a continuation-in-part application which is directed solely to subject matter adequately disclosed under 35 U.S.C. 112 in the parent nonprovisional application is entitled to the benefit of the filing date of the parent nonprovisional application."

To support the domestic priority claim, the rejected claims are mapped in the following to the specification of the parent application.

Claim 1 (Currently Amended). An apparatus for creating therapeutic charge transfer in tissue (p.7, ll 9-19), comprising a coil generating a changing magnetic field (p.10, l. 19 - p.11, l. 18) to induct an electric field in the tissue (p.7, l.11) exceeding

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1 mV/cm when said coil is 5 cm from the tissue (p.25, 1.13).

Claim 2 (Original). The apparatus according to claim 1, wherein said magnetic field is saw-tooth shaped (Fig. 7).

Claim 3 (Original). The apparatus according to claim 2, wherein said magnetic field has a growth phase and a decay phase, a duration of said growth phase being at least ten times a duration of said decay phase (Fig. 7).

Claim 14 (Original). The apparatus according to claim 1, wherein said magnetic field has an asymmetric waveform (Fig. 7).

Thus, the claims 1-3 and 14 adequately disclosed under 35 USC § 112 in the parent application. Because the instant application can claim the parent application's filing date, the instant application effectively predates Canedo. Because Canedo was filed after the priority date of the instant application, applicant respectfully believes that Canedo is unavailable as prior art.

Therefore, applicant respectfully submits that the Section 102 rejection in item 5 is now moot.

If the Examiner were not to grant the priority and remove Canedo, Canedo still does not anticipate claims 1-3 and 14. As will be explained below, the claims were patentable over the

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cited art in their original form and the claims have, therefore, not been amended to overcome the references.

Before discussing the prior art in detail, a brief review of the invention as claimed is provided. Amended claim 1 calls for an apparatus for creating therapeutic charge transfer in tissue that includes the following:

a coil generating a changing magnetic field to induct an electric field in the tissue exceeding 1 mV/cm when said coil is 5 cm from the tissue.

Although Canedo '640 teaches a coil for magnetically inducing therapeutic electric fields, Canedo does not teach "to induct an electric field ... exceeding 1 mV/cm" as provided in Claim 1 of the instant application.

The Examiner's analysis of the prior art includes a mischaracterization of Canedo '640. In item 5 of the Office action, the Examiner stated, "With reference to claims 1-3 and 14, Canedo '640 teaches a coil for inducing an electric field exceeding 1 mV/cm when the coil 119 is distanced around 5 cm from the tissue as evident in Fig. 6." (Emphasis added by Applicant.)

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Canedo '640 does not teach to induce an electric field exceeding 1 mV/cm. Although the Examiner contends that Fig. 4 indicates an output voltage from the coil, this is actually incorrect. In fact, the brief description reads as follows: "Fig. 4 shows a graphic representation of the waveform generated by the electric current supplied to the coils by the electrical circuit in all embodiments of the apparatus of this invention." (Emphasis added by Applicant.) In addition in paragraph 0104 of Canedo '640, the publications states the following: "The relationship between the instantaneous current supplied by the electric circuit to the magnetic coils as a function of time are shown as a series of waves in the forms shown in Fig. 4." (Emphasis added by Applicant.)

Fig. 4 of Canedo '640 shows a graphic indication of an average line voltage of 10 mV. It is very important to delineate between a simple voltage, which describes only the scalar value of one of a circuit's power components (voltage and current), and the description of vector component of an electric field, which is always given as electromotive force/unit of distance, such as volts/meter or mV/cm. The term "1 mV/cm" used in Claim 1 of the instant application specifies an electric field generated in space above the surface of the coil and is the output of the claimed apparatus.

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Clearly, Canedo '640 does not teach a 1 mV/cm output electric field as recited in Claim 1 of the instant application.

Claims 2-3 are patentable over Canedo '640 for the additional reason that Canedo '640 does not teach a magnetic field that is saw-tooth shaped. Claim 2 (and, therefore, claim 3, which depends on claim 2) states that the magnetic field created in the coil "is saw-tooth shaped." While, for the reasons discussed below, Applicant does not concede that the input line voltage shown in Fig. 4 is "saw toothed", even if the voltage shown in Fig. 4 were *in arguendo* considered saw-tooth shaped, the electric field shown is the input electric field and not the resulting output magnetic field. To repeat, the instant application claims a "saw-tooth shaped" magnetic field. The resulting (i.e. output) magnetic field is used to induce the output electric field in the tissue.

Although Fig.4 of Canedo '640 specifically describes only the input voltage to the coil, it might be argued that a similar shaped magnetic field would be produced by the coil. While such a result may be possible, Applicant's research and development have shown that generating such a result requires the manipulation of many variables associated with both the circuit and geometry of the coil. It is well established physics that

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coil design is not a linear progression and, therefore, variation of any parameter can and does cause large, nonlinear changes in many other parameters. Applicant asserts that it is not the classical and well-defined shape used by those with ordinary skill in the art. Applicant is a Ph.D. in physics and has spent several years developing the equipment to generate the desired magnetic saw-tooth waveform.

Even if such a similarly shaped magnetic field were produced by the coil in Canedo '640, it would not, by any possible calculation, produce an OUTPUT induced electric field greater than 10 μ v/cm (that is 1,000 times smaller than 10mv/cm described in claim 1 of the instant application). As an example, the DC portion of induced electric field according to the invention requires an INPUT voltage to the coil of 80 DC volts. That is 8,000 times greater than the average input voltage taught by Canedo '640 and 4,000 times greater than the peak input voltage taught by Canedo '640.

The invention as claimed is distinguished from Canedo '640 the resulting induced electric field is multiples of ten smaller than the electric field strength (i.e. 1 mV/cm) claimed in the current invention. To generate an electrical field having the claimed strength and magnetic waveform, the Applicant needed to

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conduct significant research and combine switches (large IGBTs) and coils in never-before known combinations. In light of this required research, the Examiner should not overextend the teachings of Canedo '640 (and likewise Ryaby and Abbott) to simply suggest a scaling up of inventions to yield a circuit that induces an electric field with the claimed strength. Although the time varying magnetic field that Canedo '640 generates will produce an induced electric output that, like those of Ryaby and Abbott, may appear similar to the electric output according to the invention of the instant application, the prior-art electric field strengths are orders of magnitude smaller. Furthermore, none of the prior-art systems can be scaled to the level that the instant application teaches using the systems and circuits disclosed in the application.

For the previously-discussed additional reasons, Canedo '640 neither teaches nor suggests generating a saw-tooth shaped magnetic field to induct an electric field having a strength of 1 mV/cm.

In item 7 of the Office action, the Examiner rejected claims 4-7 as being unpatentable over Canedo '640 in view of Tysb '400 and Kurtz '922 under 35 USC § 103(a).

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Claim 4 describes, in an apparatus for creating therapeutic charge transfer in tissue utilizing a coil to generate a changing saw-toothed magnetic field to induct an electric field in the tissue exceeding 1 mV/cm when the coil is 5 cm from the tissue, wherein the magnetic field has a growth phase lasting at least ten times a duration of a decay phase:

a control circuit controlling a current fed to said coil,

said control circuit including two subcircuits and a switch for switching between a first of said subcircuits and a second of said subcircuits,

said first of said subcircuits causing said growth phase,

said second of said subcircuits causing said decay phase.

Canedo '640 has been distinguished previously in this response.

With regard to Tsyb et al. '400, Applicants disagree with the Examiner's conclusion that Tsyb et al. '400 teaches, "A controlled switching element 5 (refer to Fig. 2) located between 'subcircuits' and connected to a unit 6 for controlling the slope of the leading edge, or growth phase of the magnetic pulses." Claims 4-7 depend on claims 2 and 3, which claim the saw-toothed magnetic field wherein the growth phase is at least ten times as long as the decay phase. The process of Tsyb et

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al. '400 will generate a single combined magnetic pulse that will produce a short DC like segment of electric field followed by a totally symmetric reversal of that electric field. Applicant's studies have shown that such symmetric waveforms do not produce the desired charge transport. A symmetric waveform merely produces a net charge transport of zero; it moves charge in one direction and then an equal amount in the opposite direction. This symmetric wave form violates the features of claims 2-3.

Applicant notes that the actual electrical field output of Tsyb et al. '400 is limited by the circuit to the same low duty cycle as those of Canedo '640, Ryaby, and Abbott; compare claims 10-11 of instant application. In column 9, lines 19-22, Tsyb et al. '400 teaches the pulse duration and number during a 2.5 minute treatment period. This allows calculation of the Duty Cycle - $50 \text{ cycles} \times 0.0003 \text{ seconds} / (2.5 \text{ minutes} \times 60 \text{ seconds/minute}) = 0.01\% (0.0001)$. At no point in the patent does Tsyb et al '400 specify an input or output current or voltage value.

Tsyb et al. '400 teaches multiple identical capacitive charging circuits that are sequentially "turned on" by a mechanical switch and then allowed to decay in the same circuit. The duty cycle demonstrated shows that there is no second decay circuit

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and thus no differential lambda that is required according to the Applicant's research. The "specify[ing of] an input or output current or voltage value" is just a further indication of Tsyb et al. failing to realize the mechanism of charge transport.

The Examiner should note that this type of work cycle is the norm for all known prior-art systems. Tsyb et al. '400 achieves a strong output voltage (which reverses) by discharging (or actually allowing to decay) a capacitor that then requires a long period to recharge. By having to wait for the decay of the capacitor, the duty cycle is significantly decreased to what Applicants generally believe is an insignificant level, especially for the healing mechanism being harnessed by the invention of the instant application.

To begin, Applicant agrees with the Examiner that the creation of the claimed magnetic field was reduced to practice by applying basic rules of physics. The Examiner stated, "Kurtz teaches that the rise and fall times, or growth and decay times ... may be controlled by the inductance of the coil." The Examiner also noted, "In view of the teachings that the resistance and inductance of each subcircuit can be varied in such a manner as to provide a time constant that may be ten

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times greater in one circuit than the other." Applicant admits that it is well known that growth and decay of magnetic fields generated by electric coils being charged or discharged obey physical laws that are dependent on the resistance, inductance, and capacitance of the circuit. Furthermore, Applicant acknowledges that it would be obvious to vary the ratios of resistance and inductance to achieve decay or growth times that can exceed ratios of 10.

With reference to Kurtz '922, Applicant believes that the prior art's misteachings of impossible to create phenomena as well as the Examiner's acceptance of them, prove that the switching according to the invention as claimed is not obvious. Applicant also notes that Fig. 11 of Kurtz '922 shows stepped increases (i.e. vertical increases) of the magnetic field of a coil generated by current pulses. However, the Examiner should recognize that empirically speaking, because of the previously-discussed physics and coil theory, such "square edged" steps would be empirically impossible because they show no growth phase. Applicant points this out to illustrate the apparent lack of obviousness to both Kurtz and the Examiner of his patent.

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Comparing Kurtz '922 to the invention of the instant application, Kurtz '922 shows no system that would produce an electric field that would produce charge transport. (Net) charge transfer is the object of the invention of the instant application.

Kurtz may have almost understood the principal (i.e. charge transport) of the invention of the instant application but ultimately failed to provide a device that would be efficient enough to apply the theory. Kurtz '922 separates the growth and decay phases of the magnetic field in order to allow the effect of the initially induced electric field not to be negated by the opposite polarity of the decay phase. Here Kurtz shows that he may have understood that the symmetrical decay of the magnetic field would not produce a therapeutic effect. Still, despite the possible realization, Kurtz was unable to devise a second circuit with a much more rapid decay time. Kurtz's teaching (i.e. waiting for a long delay between the growth and decay phase) produces a very low duty cycle as the delay time between phases reduces the time of the active initial field.

Applicants believe that the rejection in item 7 was an improper use of hindsight. The mere piecing together of elements from the prior art is not enough to form a *prima facie* case of

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obviousness. In making this rejection, the Examiner argued that because Canedo '640 (shown to be vitiated) in view of Tsyb et al. '400 (mentions a switch for a system with a duty cycle of 0.01%) and Kurtz '922 (not intended for charge transport, having errors of fact, and low duty cycle) each mentioned a feature of the claimed invention, therefore one with ordinary skill in the art would believe that the invention as claimed is obvious.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Most if not all inventions arise from a combination of old elements. See *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d

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1453,1457 (Fed. Cir. 1998). Thus, every element of a claimed invention may often be found in the prior art. See *id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. See *id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the appellant. See *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 163.5, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125,1127 (Fed. Cir. 1984).

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. See *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. See *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. See *In re*

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Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981) (and cases cited therein). Whether the examiner relies on an express or an implicit showing, the examiner must provide particular findings related thereto. See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. Broad conclusory statements standing alone are not "evidence." Id. When an examiner relies on general knowledge to negate patentability, that knowledge must be articulated and placed on the record. See *In re Lee*, 277 F.3d 1338, 1342-45, 61 USPQ2d 1430, 1433-35 (Fed. Cir. 2002).

Upon evaluation of the examiner's comments, it is respectfully believed that the evidence adduced by the examiner is insufficient to establish a *prima facie* case of obviousness with respect to the claims. Accordingly, the examiner is requested to withdraw the rejection.

Accordingly, none of the references, whether taken alone or in any combination, either show or suggest the features of claim 4. Therefore, claim 4 is patentable over the art. Moreover, because claims 5-7 are ultimately dependent on claim 4, they are believed to be patentable as well.

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In item 8 of the Office action, the Examiner rejected claim 8 as being unpatentable over Canedo '640 in view of Tsyb et al. '400, Kurtz '922 and Mangano '768 under 35 USC § 103.

Claim 8 calls for an apparatus having the following features:

a second subcircuit including an IGBT for increasing a resistance of said second subcircuit.

In item 8 of the Office action, the Examiner recapitulated that, "The combination of Canedo, Tsyb, and Kurtz disclose the invention as claimed". The examiner also states, "Mangano teaches the induction of a magnetic field within a cellular suspension. With respect to claim 8, Mangano '786 discloses and IGBT for providing enhanced current and voltage capabilities."

Unlike the invention, the magnetic field referred to by Mangano '786 is not considered as part of his disclosed application: "The electric field applied to the cell suspension is created by an electric signal applied to the electrodes; however, it is also contemplated that the electric field can be induced in the sample cell via induction by a magnetic field." This quote demonstrates that the IGBT named was not used as an inductive switch. Rather, the IGBT named is used as a switch for a

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capacitor. Mangano '786 says (col. 47, lines 57-65), "A stack of integrated bipolar transistors (IGBTs) 185 and 187, which are solid state switches that apply the electrical energy stored in the storage capacitors 184 to the PEF treatment cell."

It is again not an issue that IGBTs are used as switches for high voltage and high current applications. That is why they are made and there are well known and numerous examples of this use. The issue again is the object of the invention: inductive charge transport. The invention of the instant application teaches a novel method that combines known materials and science in a novel and non-obvious way. The IGBT component is claimed to delineate this apparatus from all others previously referenced or cited to produce induced therapeutic electrical medical treatment. Applicant's experience has shown switches and transistors fail at the necessary voltage. Therefore, the prior art using transistors or switches must not be at the high voltages demanded by the invention.

Because none of the prior art teaches using this combination in the field of induced therapeutic electrical medical treatment, the claim 8 is not obvious and patentable.

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In item 9 of the Office action, the Examiner rejected claim 9 as being unpatentable over Canedo '240 in view of Manni '976 under 35 USC § 103(a). The rejection builds on the previous rejections based on Canedo '240 and adds Manni '976 to teach a high-energy coil.

Applicant responds by reemphasizing the previously detailed distinctions between the invention and Canedo '640. Furthermore, the invention requires more than just an upscaling of the voltage. A system like in Canedo '640 is not possible to operate at significantly higher voltage due to limits imposed by basic physics. If a system like in Canedo '640 could be taken to a high voltage and then allowed to decay naturally, the decay period would be symmetrical (i.e. no charge transport) and would take a long time (i.e. low duty cycle). To overcome these problems, the Applicant has learned to switch to a second subcircuit with a high resistance created by an IGBT.

Because a mere combination of Canedo '640 with Manni '976 would not lead one with ordinary skill in the art to a device that produces effective charge transfer, the invention according to claim 9 would not be obvious.

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In item 10 of the Office action, the Examiner rejected claims 8 and 10 as being unpatentable over Canedo '640 in view of Litovitz et al. '665 under 35 USC § 103(a). The Examiner's rejection was based on the following statements. "With respect to claims 10 and 11, Litovitz teaches a coil generating a duty cycle between 10 percent and 90 percent of a field imposed on a living system (col. 12, lines 29-36)." The Examiner further stated that, "Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to have incorporated the duty cycle as taught by Litovitz to the invention of Canedo in order to retain an effective therapeutic field."

Litovitz '665 shows very clearly that the duty cycle to which he refers is for the purpose of interrupting exposure to electromagnetic radiation in the near 60 Hertz range, which he deems to be detrimental. He has examples of this in his Figs. 3, 4, 5, 6, and 7. His preferred method is to actually superimpose a modulating field on the incoming line signals that are a direct electrical connection to the circuit. He does mention that a similar effect may be obtained by alternately powering a coil on and off to produce an interfering electromagnetic field near the environment to be protected: that is, turn on and off the power to an electric coil to modulate

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the source of an external electromagnetic signal. In the citation given, he says, "Another method of modulating the detrimental field is by using square wave modulation. That is, interrupt the power delivered at a regular interval. The modulation frequency should be preferably of the order of one second, as guided by the Litovitz invention. The interruption time should be preferably between 0.1 and 0.9 seconds, corresponding to a duty cycle between 10% and 90%."

The term duty cycle can have more than one interpretation. It is usually defined as the percentage of time during the operation of a system in which it is doing work. It can also refer to that portion of a single cycle that is doing work. In claims 10 and 11 of the instant application, the duty cycle is referencing the on and off periods within each cycle of electric field generated by the machine. Because the same waveform inducing the electric field is repeated continuously without any intervening time for the entirety of the treatment period, the duty cycle of one wave period would be the same as the duty cycle for the entire exposure time of the treatment.

Beyond the admittedly obvious significance of increased efficiency, Applicants have found that duty cycle is critical to achieve charge transport. For a high energy electric coil to

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charge and discharge in the manner needed to achieve a duty cycle of 80%, the coil must have the very specific circuits taught in the instant application. To make it very plain, no system mentioned in the Detailed Action has the ability to produce continuously repetitive induced electric fields of output electric field strengths where the active DC like component of the cycle is both 80% of the cycle and greater than or equal to 1 mv/cm.

The specific duty cycle claimed is necessary to produce charge transport. Litovitz produces only a weak signal at approximately 60 Hertz, which according to Litovitz, is intended to "confuse the biologic cell so that it can no longer respond to the usual fields found in the home and work place." One with ordinary skill in the art reading Litovitz would require a great leap of insight to move from the teaching of Litovitz to reach the combination of claims 10-11. Litovitz teaches that a signal turned on and off at any duty cycle and can be used to "confuse" other low-energy, low-frequency signals. This does not suggest that modifying the duty cycle of Canedo '640 according to Litovitz would result in therapeutic charge transfer in tissue. Therefore, one reading Canedo '640 in light of Litovitz would not think that claims 10-11 are obvious.

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In item 11 of the Office action the Examiner rejected claims 12 and 13 as being unpatentable over Canedo '640 in view of Day et al. '210 under 35 U.S.C. § 103(a).

Applicants acknowledge that liquid coolant systems are not novel in and of themselves. However, when combined with the system as taught by Applicant (for the reasons discussed previously), the combination is patentable. Still, the invention of the instant application is running at such higher powers than those taught by the prior art in the therapeutic field that none have need liquid coolant systems. It is well known that the amount of heat produced by current passing through a wire is proportional to the electrical current squared, multiplied by the total resistance of the wire, $H = i^2 \times R$. The purpose of claims 12-13 was to delineate the coil required by the invention of the instant application, which requires a special cooling apparatus because of the amount of electrical power it uses. All cited prior-art inductive therapeutic systems do not require liquid cooling. This is because they are all incapable, by reason of the circuit design, of carrying high levels of continuous input current and thus incapable of providing the requisite output electric field required to produce charge transport of sufficient quantity to effect the desired therapeutic result. This suggests that the invention as claimed is more than a mere

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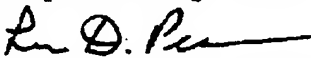
scaling up of devices like Canedo '640. Scaling up of the prior art, if possible, would lead to unforeseen challenges like a cooling system. For these reasons, the invention as described in claims 12-13 would not be obvious to one with ordinary skill in the art when reading Canedo '640 in view of Day et al. '210.

In view of the foregoing, reconsideration and allowance of claims 1-30 are solicited. In the event the Examiner should still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted.

A payment of \$250 is attached to provide for the small-entity fee for ten additional total claims.

If an extension of time for this paper is required, petition for extension is herewith made.

Respectfully submitted,


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